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EXAMINER	
FORD, ALLISON M	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/822,222	SCHMITT ET AL.	
	Examiner	Art Unit	
	Allison M Ford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-49* is/are rejected.

7)☐ Claim(s) *4,6 and 24* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

Claims 1-49 are pending in the current application.

Claim Objections

Claim 4 is objected to because of the following informalities: it appears the claim should read, "...wherein said first enzyme is phospholipase A1 and/or A2." Appropriate correction is required.

Claims 6 and 24 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 6 and 24 require the second enzyme to effectively hydrolyze the triglyceride under the reaction conditions; it is required in both independent claims 1 and 18 that the second enzyme be a lipase that is effective to hydrolyze the triglyceride.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-28 and 37-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's claims 1, 18, 37, 42 and their dependents require the respective methods to occur "under conditions effective to inhibit esterification of said hydrolyzed phospholipid with released fatty acids." Applicant has failed to clearly define what conditions effectively inhibit esterification of said hydrolyzed phospholipid with released fatty acids. In the specification applicant provides several possible conditions which may inhibit esterification, including addition of a salt or weak base, such as calcium chloride, use of a membrane that removes any fatty acids from the reaction mixture, or, in the case of an organic solvent, providing an effective water content to promote hydrolysis over transesterification (See Specification, Pg. 10-11). These preferred modifications do not constitute a sufficient definition of the exact conditions which applicant is intending to claim in claims 1-28 and 37-49. Therefore, with no clear definition of the claimed conditions applicant has failed to clearly convey what they have invented, and therefore has also failed to put the public in possession of the claimed invention. See *In re Barker*, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977) and *Eli Lilly,* 119F. 3d. at 1568, 43 USPQ2d at 1406. See MPEP § 2163.

Claims 4, 5, 15, 22 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's claims 1 and 18 require the "first enzyme" to be a phospholipase or lipase effective to hydrolyze the phosphatidyl component of the lecithin, which applicant calls hydrolysis of the phospholipid component; therefore the "first enzyme" must be phospholipase C, which hydrolyzes the ester bond between the glycerol backbone and the phosphatidyl group, or phospholipase D, which hydrolyzes the ester bond between the phosphatidyl head group and the phosphate group. Phospholipases A1 or A2 do not hydrolyze the phosphatidyl component of the phospholipid; phospholipases A1 and A2

hydrolyze the ester bonds between the glycerol backbone and the acyl side chains, applicant calls this hydrolysis of the triglyceride. Therefore applicant is not enabled to use phospholipases A1 and/or A2 as the "first enzyme" in the methods of claim 1, or in the method of claim 18 when the enzymes are added sequentially.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's claims 1, 18, 37, 42 and their dependents require the respective methods to occur "under conditions effective to inhibit esterification of said hydrolyzed phospholipid with released fatty acids." The specific conditions that inhibit esterification are not clearly described, neither in the claims nor in the specification; therefore these conditions are unclear.

Applicant's claims 1, 4, 5, 14, 15, 18, 22 and 23 are further rejected as being unclear. Claims 1 and 18 require the "first enzyme" to be a phospholipase or lipase effective to hydrolyze phospholipid component; it is not clear what the "phospholipid component" of lecithin is, as lecithin consists, in large part, of phospholipids. It appears applicant is referring to the phosphatidyl component of phospholipids; therefore the "first enzyme" must hydrolyze one of the two ester bonds of the phosphatidyl group; thus the "first enzyme" must be phospholipase C, which hydrolyzes the ester bond between the glycerol backbone and the phosphatidyl group, or phospholipase D (Claim 14), which hydrolyzes the ester bond between the phosphatidyl head group and the phosphate group. Phospholipases A1 or A2 do not hydrolyze the ester bonds of the phosphatidyl group; phospholipases A1 and A2 hydrolyze the ester bonds between the glycerol backbone and the acyl side chains, applicant calls this hydrolysis of the

triglyceride (Claims 4, 5, 15, 22 and 23). Therefore it is not clear which enzymes applicant is intending to use, and which bonds are to be hydrolyzed, in the first and second steps of claims 1 or 18.

Applicant's claim 23 is self-dependent. The metes and bounds of the claim cannot be determined.

Applicant's claim 29 recites the limitation "the conditions," there is insufficient antecedent basis for this limitation in the claim, as no conditions have been defined. Additionally, it is confusing what is meant by "under the conditions of said contacting," it would be remedial to delete this phrase. Claims 30-36 have the limitations of claim 29 and therefore are rejected on the same basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18, 19, 22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Pardun (US Patent 3,652,397).

Pardun teaches a method for preparing a hydrolyzed phosphatide emulsifying agent (which applicant calls a hydrolyzed lecithin product), comprising hydrolyzed phospholipids, monoglycerides, and diglycerides, the method comprising contacting unhydrolyzed vegetable phosphatide, in an organic solvent medium, preferably hexane (which applicant calls an aprotic organic solvent medium) with an enzyme preparation comprising both phospholipase A and lipase (See col. 2, ln 11-50 & claims 1-3). The phosphatide compositions comprise phosphatidylcholine and, to a lesser extent, phosphatidylethanolamine; therefore it is a lecithin materials that comprises a phospholipid component

and a triglyceride component. The phosphatides are exposed to both enzymes simultaneously. Therefore the reference anticipates the claimed subject matter.

Claims 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Haas et al (J of the Am. Oil Chem. Soc., 1994).

Haas et al teach a method of producing a hydrolyzed lecithin product, comprising contacting soybean phosphatidylcholine (which applicant calls a lecithin material, comprising a phospholipid component and a triglyceride component), in water-saturated hexane (an organic solvent) with lipases from a variety of microorganisms (See Pg. 483-484 & Table 2). Therefore the reference anticipates the claimed subject matter.

Claim 29 is rejected under 35 U.S.C. 102(b) as being anticipated by VanMiddlesworth et al (J. Org. Chem., 1992).

VanMiddlesworth et al teach a method of producing a hydrolyzed lecithin product, comprising contacting soybean phosphatidyl inositol (which applicant calls a lecithin material, comprising a phospholipid component and a triglyceride component), in an aqueous solution of deoxycholate, bovine serum albumin, $CaSO_4$ and borate buffer with *Rhizopus arrhizus* lipase. The lipase effectively hydrolyzes the primary ester on the triglyceride backbone to produce a monoglyceride (See Pg. 4753-4754). Therefore the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-7, 11, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sas et al (US Patent 6,068,997), in view of Hattori et al (US Patent 5,378,623).

Sas et al teach a method of producing hydrolyzed lecithin product comprising hydrolyzed phospholipids, monoglycerides, and diglycerides, by contacting a lecithin material, that comprises a phospholipid component and a triglyceride component, with a blend of lipase and phospholipase A2 in an aqueous solvent medium. The lipase cleaves ester bonds of the lipids and produces glycerol and mono- and diglycerides. The phospholipase A2 cleaves the ester bonds of the phospholipids at the C2 position of the glycerol backbone. The result is a hydrolyzed lecithin product comprising lyso-phospholipids (See col. 1, ln 45-62).

Additionally, though Sas et al only teach the use of lipase and phospholipase A2, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use any enzyme that effectively hydrolyzes an ester bond in a phospholipid, including phospholipases A1, A2, C, D, and/or lipase (See Hattori et al, col. 1, ln 11-28). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use any combination of the enzymes mentioned above to hydrolyze a lecithin material to produce a hydrolyzed lecithin material; therefore one of ordinary skill in the art would have been motivated to expose a lecithin material first to a phospholipase D or phospholipase C to hydrolyze the ester bonds on either side of the phosphodiester linkage of a phospholipid (which applicant calls hydrolyzing the phospholipid) to produce phosphatidic acid or a diglyceride, respectively, and then expose the reaction product to a lipase effective to hydrolyze the ester bonds between the glycerol backbone and the acyl groups (which applicant calls hydrolyzing the triglyceride) (Claim 1). Alternatively, it would have been obvious to expose the lecithin material to phospholipase A1 and/or A2 first to cause specific cleavage of the fatty acids, and subsequently exposing the product to a lipase that has less specific activity to cleave other ester bonds remaining in the phospholipid (Claims 4 and 5). Still

further, it would have been obvious to one of ordinary skill in the art to first contact the lecithin material with a phospholipase D, to create phosphatidic acid, and then subsequently contact the phosphatidic acid with a phospholipase A1 and/or A2 to further cause hydrolysis of the acyl groups to produce monoglycerides, and then further contact the product with a lipase to hydrolyze any remaining ester bonds (Claims 14 and 15).

One of ordinary skill in the art would have been motivated to contact a lecithin material comprising a phospholipid component and a triglyceride component with any or all of the enzymes capable of hydrolyzing the lecithin material. One would have been motivated to contact a lecithin material with any or all of the enzymes mentioned above in order to produce a hydrolyzed lecithin material. It is well known in the art that phospholipase A1, A2, C, D and lipase all hydrolyze ester bonds within phospholipid molecules (generically, lecithin) to produce hydrolyzed phospholipids, mono- and diglycerides in various proportions and structures (See, for example, Hattori et al). One would have been motivated to produce hydrolyzed lecithins because it is well known in the art that hydrolyzed lecithins have improved emulsifying capabilities (See, e.g., Sas et al, col. 1, ln 36-39); therefore one would be motivated to hydrolyze native lecithin, using any or all of the enzymes mentioned above, to produce the desired hydrolyzed phospholipids, mono- and diglycerides. One of ordinary skill in the art would be motivated to use the enzymes in any combination and order because the enzymes, especially the phospholipases, have specific cleavage sites, the use of one enzyme does not effect the action of another enzyme. The reaction product of a first enzyme with the lecithin material is not necessary for subsequent hydrolyzations by different enzymes. For example, if one was using enzymes immobilized on stirs, and contact with the lecithin material involved stirring the lecithin material with the enzyme-coated stir, it would be a matter of design choice which order one wished to use the various enzyme-coated stirs. One would expect success producing the hydrolyzed lecithin product claimed using any or all of the enzymes described above because the exact proportions and structures of the hydrolyzed products are not

important, only that the resulting product is hydrolyzed lecithin. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1, 8-10, 16, 17, 23, 27, 28 and 35-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sas et al (US Patent 6,068,997), in view of Hattori et al (US Patent 5,378,623), Haas et al (J of Am. Oil Chem. Soc, 1994) and Chung et al (US Patent 6,773,902).

Sas et al teach a method of producing hydrolyzed lecithin product comprising hydrolyzed phospholipids, monoglycerides, and diglycerides, by contacting a lecithin material, which comprises a phospholipid component and a triglyceride component, with a blend of lipase and phospholipase A2 in an aqueous solvent medium. The lipase cleaves ester bonds of the lipids and produces glycerol and mono- and diglycerides. The phospholipase A2 cleaves the ester bonds of the phospholipids at the C2 position of the glycerol backbone. The result is a hydrolyzed lecithin product comprising lyso-phospholipids (See col. 1, ln 45-62).

Additionally, though Sas et al only teach the use of lipase and phospholipase A2, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use any enzyme that effectively hydrolyzes an ester bond in a phospholipid, including phospholipases A1, A2, C, D, and/or lipase (See Hattori et al, col. 1, ln 11-28). See teachings above. Additionally, though Sas et al teach performing the contact in an aqueous solvent medium, it would have been obvious to one of ordinary skill in the art to perform the contact in an aprotic, organic solvent medium, for example, hexane. The aforementioned enzymes all retain their activity in organic solvents: Hattori et al teach that phospholipase A1 may perform phospholipid hydrolysis in hexane (see col. 12, ln 20-26); Haas et al teach lipase hydrolyzes phospholipids in hexane (See Pg. 483, col. 2); and Chung et al teach phospholipase A2 also performs hydrolysis of phospholipids in organic solvents (See col. 4, ln 35-42). Therefore it would have

been obvious to one of ordinary skill in the art at the time the invention was made to produce hydrolyzed lecithin products by contacting lecithin material with phospholipase A1, A2, C, D and/or lipases, in any order and combination in an organic solvent, such as hexane. One would have been motivated to perform the contact in an organic solvent because extraction of lecithin material from oil seeds is often performed through solubilization of the native lecithin in an organic solvent; by performing the enzymatic contact in the organic solvent one saves the step of evaporating the organic solvent before hydrolyzing the lecithin. One would expect success because all the enzymes are effective in organic solvents, as taught by Hattori et al, Haas et al, and Chung et al.

Finally, the exact concentrations of mono- and diglycerides, the acetone insoluble content and the acid value of the hydrolyzed lecithin product produced in the method of Sas et al, or in a method similar to that of Sas et al wherein any of the enzymes phospholipases A1, A2, C, D and/or lipase, in any combination and order, as described above, are result effective variables that would be optimized by one of ordinary skill in the art. The concentration of mono- and diglycerides in the resulting hydrolyzed product directly depends from the combination of enzymes used, and the length of the reaction time. Clearly, the length of the reaction time directly affects the degree of hydrolysis and, therefore, the percentage of mono- and diglycerides (Claims 41 and 46). Similarly, the acid value is a direct result of the reaction time and the degree of hydrolysis that occurs. Additionally, the acetone insoluble content is representative of the amount of phospholipids present in the lecithin material; depending on the purity of the native lecithin, the percentage of phospholipids initially present in the material, and the degree of hydrolysis by phospholipase C (which removes the phosphatidyl group from the phospholipid) and non-specific lipases (which can also hydrolyze the ester bond between the glycerol backbone and the phosphatidyl group), the acetone insoluble content can be altered. Therefore, by increasing the phospholipid content of the starting lecithin material, by purification, or by purchasing a lecithin material with a desired high acetone insoluble content, and by eliminating the use of phospholipase C, one of

ordinary skill in the art can increase the acetone insoluble content to above 60% (Claims 16, 17, 27, 28 and 35-49).

Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 2, 3, 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sas et al (US Patent 6,068,997), in view of Hattori et al (US Patent 5,378,623), Haas et al (J. Am. Oil Chem. Soc, 1994) and Chung et al (US Patent 6,773,902), further in view of Jirjis et al (US 2003/0072856 A1).

Sas et al teach a method of producing hydrolyzed lecithin product comprising hydrolyzed phospholipids, monoglycerides, and diglycerides, by contacting a lecithin material, which comprises a phospholipid component and a triglyceride component, with a blend of lipase and phospholipase A2 in an aqueous solvent medium. The lipase cleaves ester bonds of the lipids and produces glycerol and mono- and diglycerides. The phospholipase A2 cleaves the ester bonds of the phospholipids at the C2 position of the glycerol backbone. The result is a hydrolyzed lecithin product comprising lyso-phospholipids (See col. 1, ln 45-62).

Additionally, though Sas et al only teach the use of lipase and phospholipase A2, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use any enzyme that effectively hydrolyzes an ester bond in a phospholipid, including phospholipases A1, A2, C, D, and/or lipase (See Hattori et al, col. 1, ln 11-28). Additionally, it would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the contact in an organic solvent medium, such as hexane, since all the enzymes will effectively hydrolyze phospholipids in organic solvents. See teachings above.

Though neither Sas et al nor Hattori et al teach obtaining the lecithin material through a membrane degumming process, it would have been obvious to one of ordinary skill in the art at the time the invention was made to obtain the native lecithin by performing a membrane degumming process and

collecting the retentate, such as taught by Jirjis et al. Jirjis et al teach a method of obtaining lecithin material as a by-product of a membrane degumming processes of soybean oil, comprising processing oil seeds to produce crude vegetable oil, dissolving the crude vegetable oil in a hydrocarbon solvent to produce vegetable oil miscella, feeding the solution comprising the miscella to a series of membranes, and recovering the retentate (stream that does not pass through the membrane) from the second phospholipid filter (permeated through first phospholipid filter that filter out large solids, does not permeate through second phospholipid filters that filter out phospholipids); this retentate comprises a lecithin product containing up to 85% phospholipids (See Pg. 2, paragraphs 0012-0013 and Pg 4, paragraph 0033-0037).

One of ordinary skill in the art would have been motivated to obtain the lecithin as the retentate from a membrane degumming process, such as that taught by Jirjis et al, in the method of Sas et al because the membrane filters out the large solid impurities, thereby making the lecithins obtained via the membrane degumming process have fewer impurities than lecithins obtained by water degumming processes. One would have been motivated to obtain a lecithin material with a high concentration of phospholipids by performing the membrane degumming process of Jirjis et al because Sas et al's process is specifically designed to hydrolyze phospholipids, therefore a higher concentration of phospholipids in the starting lecithin material would equate to a greater amount of hydrolyzed phospholipids in the method of Sas et al. One would have expected success because using the lecithin obtained from the retentate of the membrane degumming process of Jirjis et al in the method of Sas et al because Sas et al's method utilizes lecithin, how the lecithin material is obtained does not effect the method or the outcome.

Furthermore, though Sas et al, Hattori et al, Chung et al nor Haas et al teach performing the method of hydrolyzing the lecithins, either in aqueous or organic solvent medium, in the presence of a membrane effective to separate the hydrolyzed phospholipids, monoglycerides, and diglycerides from the released fatty acids, it would have been obvious to one of ordinary skill in the art at the time the invention

was made to use the membrane system of Jirjis et al to effectively separate the smaller, released fatty acids from the desired hydrolyzed phospholipids, mono- and diglycerides. One of ordinary skill in the art would have been motivated to filter out the released fatty acids via a membrane filtration system in order to obtain a retentate of hydrolyzed phospholipids and mono- and diglycerides because these modified lecithins are desirable for uses in the food and pharmaceutical industries, while the released fatty acids are not. One would have expected success because Jirjis et al teach a simple system of membranes that can effectively separate out molecules based on molecular size and weight; therefore the smaller, lighter released fatty acids could be filtered out of a solution comprising the fatty acids and the larger hydrolyzed lecithins, leaving only the hydrolyzed lecithins as the desired retentate.

Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 18-22 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pardun (US Patent 3,652,397), in view of Jirjis et al (US 2003/0072856 A1).

Pardun teaches a method for preparing a hydrolyzed phosphatide emulsifying agent (which applicant calls a hydrolyzed lecithin product), comprising hydrolyzed phospholipids, monoglycerides, and diglycerides, the method comprising contacting unhydrolyzed vegetable phosphatide, in an organic solvent medium, preferably hexane (which applicant calls an aprotic organic solvent medium) with an enzyme preparation comprising both phospholipase A and lipase (See col. 2, ln 11-50 & claims 1-3) (Claims 18, 22, 24). The phosphatide compositions comprise phosphatidylcholine and, to a lesser extent, phosphatidylethanolamine; therefore it is a lecithin materials that comprises a phospholipid component and a triglyceride component. The phosphatides are exposed to both enzymes simultaneously (Claim 19).

Pardun obtains the crude phosphatides (which applicant calls lecithin material) as a by-product of the solvent-extraction of oil seeds for edible oil production. The phosphatides are precipitated as slimes

by steam, and then separated by centrifugation, and then dried and evaporated under pressure (See col. 1, ln 4-17).

Though Pardun does not teach the lecithin to be a retentate from a vegetable oil membrane degumming process, it would have been obvious to one of ordinary skill in the art at the time the invention was made to obtain the crude phosphatides (which applicant calls lecithin material) by performing a membrane degumming process and collecting the retentate, such as taught by Jirjis et al. Jirjis et al teach a method of obtaining lecithin material as a by-product of a membrane degumming processes of soybean oil, comprising processing oil seeds to produce crude vegetable oil, dissolving the crude vegetable oil in a hydrocarbon solvent to produce vegetable oil miscella, feeding the solution comprising the miscella to a series of membranes, and recovering the retentate (stream that does not pass through the membrane) from the second phospholipid filter (permeated through first phospholipid filter that filter out large solids, does not permeate through second phospholipid filters that filter out phospholipids); this retentate comprises a lecithin product containing up to 85% phospholipids (See Pg. 2, paragraphs 0012-0013 and Pg 4, paragraph 0033-0037) (Claims 20, 21 & 25).

One of ordinary skill in the art would have been motivated to obtain the lecithin as the retentate from a membrane degumming process, such as that taught by Jirjis et al, in the method of Pardun because the membrane filters out the large solid impurities, thereby making the lecithins obtained via the membrane degumming process have fewer impurities than lecithins obtained by water degumming processes. One would have been motivated to obtain a lecithin material with a high concentration of phospholipids by performing the membrane degumming process of Jirjis et al because Pardun's process is specifically designed to hydrolyze phospholipids, therefore a higher concentration of phospholipids in the starting lecithin material would equate to a greater amount of hydrolyzed phospholipids in the method of Pardun. One would have expected success because using the lecithin obtained from the retentate of the membrane degumming process of Jirjis et al in the method of Pardun because Pardun's method utilizes

phosphatides (lecithin material), how the lecithin material is obtained does not effect the method or the outcome.

Furthermore, though Pardun does not teach performing the method of hydrolyzing the phosphatides in the presence of a membrane effective to separate the hydrolyzed phospholipids, monoglycerides, and diglycerides from the released fatty acids, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the membrane system of Jirjis et al to effectively separate the smaller, released fatty acids from the desired hydrolyzed phospholipids, mono- and diglycerides. One of ordinary skill in the art would have been motivated to filter out the released fatty acids via a membrane filtration system in order to obtain a retentate of hydrolyzed phospholipids and mono- and diglycerides because these modified lecithins are desirable for uses in the food and pharmaceutical industries, while the released fatty acids are not. One would have expected success because Jirjis et al teach a simple system of membranes that can effectively separate out molecules based on molecular size and weight; therefore the smaller, lighter released fatty acids could be filtered out of a solution comprising the fatty acids and the larger hydrolyzed lecithins, leaving only the hydrolyzed lecithins as the desired retentate (Claim 26).

Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haas et al (J of the Am. Oil Chem. Soc., 1994), in view of Jirjis et al (US 2003/0072856 A1).

Haas et al teach a method of producing a hydrolyzed lecithin product, comprising contacting soybean phosphatidylcholine (which applicant calls a lecithin material, comprising a phospholipid component and a triglyceride component), in water-saturated hexane (an organic solvent) with lipases from a variety of microorganisms (See Pg. 483-484 & Table 2).

Haas et al obtain the soybean phosphatidylcholine (lecithin material) from a commercial source, already processed. However, though Haas et al does not produce the lecithin material from seeds, specifically as the retentate from a process of vegetable oil membrane degumming, it would have been obvious to one of ordinary skill in the art at the time the invention was made to obtain the soybean phosphatidylcholine (which applicant calls lecithin material) by performing a membrane degumming process and collecting the retentate, such as taught by Jirjis et al. Jirjis et al teach a method of obtaining lecithin material as a by-product of a membrane degumming processes of soybean oil, comprising processing oil seeds to produce crude vegetable oil, dissolving the crude vegetable oil in a hydrocarbon solvent to produce vegetable oil miscella, feeding the solution comprising the miscella to a series of membranes, and recovering the retentate (stream that does not pass through the membrane) from the second phospholipid filter (permeated through first phospholipid filter that filter out large solids, does not permeate through second phospholipid filters that filter out phospholipids); this retentate comprises a lecithin product containing up to 85% phospholipids (See Pg. 2, paragraphs 0012-0013 and Pg 4, paragraph 0033-0037) (Claims 31-33).

One of ordinary skill in the art would have been motivated to obtain the lecithin as the retentate from a membrane degumming process, such as that taught by Jirjis et al, for use in the method of Haas et al if one wanted to produce their own lecithin material instead of purchasing it from a commercial source. One would have been motivated to use the membrane degumming process of Jirjis et al because the membrane filters out the large solid impurities, thereby making the lecithins obtained via the membrane degumming process have fewer impurities than lecithins obtained by water degumming processes, thereby producing a more substantially pure lecithin material that comprises a high concentration of phospholipids (including phosphatidylcholine). One would have been motivated to obtain a lecithin material with a high concentration of phospholipids by performing the membrane degumming process of Jirjis et al because Haas et al's process is specifically designed to hydrolyze phospholipids, therefore a

higher concentration of phospholipids in the starting lecithin material would equate to a greater amount of hydrolyzed phospholipids in the method of Haas et al. One would have expected success because using the lecithin obtained from the retentate of the membrane degumming process of Jirjis et al in the method of Haas et al because Haas et al's method utilizes phospholipids (lecithin material), how the lecithin material is obtained does not effect the method or the outcome.

Furthermore, though Haas et al do not teach performing the method of hydrolyzing the phosphatides in the presence of a membrane effective to separate the hydrolyzed phospholipids, monoglycerides, and diglycerides from the released fatty acids, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the membrane system of Jirjis et al to effectively separate the smaller, released fatty acids from the desired hydrolyzed phospholipids, mono- and diglycerides. One of ordinary skill in the art would have been motivated to filter out the released fatty acids via a membrane filtration system in order to obtain a retentate of hydrolyzed phospholipids and mono- and diglycerides because these modified lecithins are desirable for uses in the food and pharmaceutical industries, while the released fatty acids are not. One would have expected success because Jirjis et al teach a simple system of membranes that can effectively separate out molecules based on molecular size and weight; therefore the smaller, lighter released fatty acids could be filtered out of a solution comprising the fatty acids and the larger hydrolyzed lecithins, leaving only the hydrolyzed lecithins as the desired retentate (Claim 34).

Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over VanMiddlesworth et al (J. Org. Chem., 1992), in view of Jirjis et al (US 2003/0072856 A1).

VanMiddlesworth et al teach a method of producing a hydrolyzed lecithin product, comprising contacting soybean phosphatidyl inositol (which applicant calls a lecithin material, comprising a phospholipid component and a triglyceride component), in an aqueous solution of deoxycholate, bovine serum albumin, $CaSO_4$ and borate buffer with *Rhizopus arrhizus* lipase. The lipase effectively hydrolyzes the primary ester on the triglyceride backbone to produce a monoglyceride (See Pg. 4753-4754).

VanMiddlesworth et al is silent on how or where the phosphatidyl inositol was obtained; it appears it was purchased commercially, already purified. However, though VanMiddlesworth et al does not produce the lecithin material from seeds, specifically as the retentate from a process of vegetable oil membrane degumming, it would have been obvious to one of ordinary skill in the art at the time the invention was made to obtain the phosphatidyl inositol (which applicant calls lecithin material) by performing a membrane degumming process and collecting the retentate, such as taught by Jirjis et al. Jirjis et al teach a method of obtaining lecithin material as a by-product of a membrane degumming processes of soybean oil, comprising processing oil seeds to produce crude vegetable oil, dissolving the crude vegetable oil in a hydrocarbon solvent to produce vegetable oil miscella, feeding the solution comprising the miscella to a series of membranes, and recovering the retentate (stream that does not pass through the membrane) from the second phospholipid filter (permeated through first phospholipid filter that filter out large solids, does not permeate through second phospholipid filters that filter out phospholipids); this retentate comprises a lecithin product containing up to 85% phospholipids (See Pg. 2, paragraphs 0012-0013 and Pg 4, paragraph 0033-0037) (Claims 31-33).

One of ordinary skill in the art would have been motivated to obtain the lecithin as the retentate from a membrane degumming process, such as that taught by Jirjis et al, for use in the method of VanMiddlesworth et al if one wanted to produce their own lecithin material instead of purchasing it from a commercial source. One would have been motivated to use the membrane degumming process of Jirjis et al because the membrane filters out the large solid impurities, thereby making the lecithins obtained via

the membrane degumming process have fewer impurities than lecithins obtained by water degumming processes, thereby producing a more substantially pure lecithin material that comprises a high concentration of phospholipids. One would have been motivated to obtain a lecithin material with a high concentration of phospholipids by performing the membrane degumming process of Jirjis et al because VanMiddlesworth et al's process is specifically designed to hydrolyze phospholipids, therefore a higher concentration of phospholipids in the starting lecithin material would equate to a greater amount of hydrolyzed phospholipids in the method of VanMiddlesworth et al. One would have expected success because using the lecithin obtained from the retentate of the membrane degumming process of Jirjis et al in the method of VanMiddlesworth et al because VanMiddlesworth et al's method utilizes phospholipids (lecithin material), how the lecithin material is obtained does not effect the method or the outcome.

Furthermore, though VanMiddlesworth et al do not teach performing the method of hydrolyzing the phosphatides in the presence of a membrane effective to separate the hydrolyzed phospholipids, monoglycerides, and diglycerides from the released fatty acids, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the membrane system of Jirjis et al to effectively separate the smaller, released fatty acids from the desired hydrolyzed phospholipids, mono- and diglycerides. One of ordinary skill in the art would have been motivated to filter out the released fatty acids via a membrane filtration system in order to obtain a retentate of hydrolyzed phospholipids and mono- and diglycerides because these modified lecithins are desirable for uses in the food and pharmaceutical industries, while the released fatty acids are not. One would have expected success because Jirjis et al teach a simple system of membranes that can effectively separate out molecules based on molecular size and weight; therefore the smaller, lighter released fatty acids could be filtered out of a solution comprising the fatty acids and the larger hydrolyzed lecithins, leaving only the hydrolyzed lecithins as the desired retentate (Claim 34).

Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 37, 39, 41, 42, 44 and 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over 't Hooft et al (US 2002/0122867 A1).

Applicant's claims 37, 42 and 47 are drawn to a hydrolyzed lecithin product produced by various methods. Therefore, the products as claimed are determined to be product-by-process claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the products themselves. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

't Hooft et al teach a hydrolyzed sunflower lecithin product produced by the reaction of phospholipase A2 with native sunflower lecithin, obtained from Cereol Novenyollajipari R T, Budapest, for 30 minutes that has a acetone insoluble fraction of 56.5 wt % and an acid value of 39.9 mg KOH/g (See Pg. 4, paragraph 0058 and Table 1). The hydrolyzed lecithin product (after 30 min reaction) contains 11.3 wt % phosphatidylcholine (a diglyceride), 7.5 wt % phosphatidyl inositol (a diglyceride), 2.6 phosphatidylethanolamine (a diglyceride), 2.9 wt % lyso-phosphatidylcholine (a monoglyceride), 0.7 wt % lyso-phosphatidyl inositol (a monoglyceride), and 0.9 wt % lyso-phosphatidylethanolamine (a monoglyceride), for a total mono/diglyceride content of 25.9 wt % (See Table 1, Pg. 4) (Claims 41 and 46). However, as the reference clearly indicates, the acetone insoluble fraction and the acid value are result effective variables. 't Hooft et al show that the acid value increases with the reaction time, therefore it would be obvious to one of ordinary skill in the art would be able to determine the appropriate reaction time to produce a hydrolyzed lecithin product with an acid value of less than 45 mg KOH/g,

without undue experimentation. Additionally, as 't Hooft et al show, the acetone insoluble fraction of a native lecithin material varies depending on the phospholipid content; lecithins with different acetone insoluble fractions are available from various vendors, for example, 'Bolec' lecithins obtained from Unimills, Zwijndrecht, Netherlands have an acetone insoluble fraction of 62 wt %, while the lecithins obtained from Cereol Novenyollajipart R T, Magyargorszag, Budapest, have an acetone insoluble fraction of 56.5 wt % (See Pg. 4, paragraph 0066-0067). Therefore, one of ordinary skill in the art would know to choose a native lecithin with an appropriate phospholipid content, to have an acetone insoluble content of at least 60%, or one could purify the hydrolyzed lecithin product obtained by means of filtration or other means well known in the art to increase the phospholipid content, and thus increase the acetone insoluble fraction. Therefore, though 't Hooft et al do not teach a hydrolyzed lecithin product with an acid value of less than 45 mg KOH/g and an acetone insoluble fraction of at least 60 wt %, it would have been obvious to one of ordinary skill in the art to choose a lecithin material with a higher acetone insoluble fraction, or to purify the hydrolyzed lecithin product to increase the acetone insoluble fraction after hydrolysis. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allison M Ford
Examiner
Art Unit 1651

LEON B. LANKFORD, JR.
PRIMARY EXAMINER